

PATENT  
Attorney Docket No.:  
053665-5005-02

162  
L  
J

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Kucera, et al.

Serial No.: 09/412,539

Filed: October 4, 1999

For: LIPID ANALOGS FOR TREATING  
VIRAL INFECTIONS

Group Art Unit: 1624

Examiner: B. L. Coleman

RECEIVED

MAY 08 2003

TECH CENTER 1600/2900

INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 C.F.R. §§ 1.56 ET SEQ.

Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Dear Sir:

In accordance with 37 C.F.R. § 1.97(b), the above-identified Applicants cite the following patents and publications, which may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. § 1.56. This Information Disclosure Statement is being filed before the mailing date of the Final Office Action and a Petition and the required fee set forth in §1.17(p) is being submitted simultaneously herewith.

In compliance with 37 C.F.R. § 1.98(a), copies of the patents and publications set forth below and listed on the attached Form PTO-1449 (3 sheets) are provided.

CERTIFICATE OF MAILING (37 C.F.R. § 1.8)

I hereby certify that this paper, and the papers and/or fees referred to herein as transmitted, submitted or enclosed, are being deposited on the date shown below with the U.S. Postal Service with sufficient postage as first-class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Name Kim R. Jessum Signature

*Kim R. Jessum*

Date of Deposit May 1, 2003

U.S. Patents

<u>Patent No.</u>	<u>Issue Date</u>	<u>Patentee</u>
4,221,732	9/9/80	Oette et al.
4,797,479	1/10/89	Shuto et al.
4,997,761	3/5/91	Jett-Tilton

Foreign Publications

<u>Publication No.</u>	<u>Publication Date</u>	<u>Country</u>
WO 93/00910	1/21/93	WO
EP 0 350 287	1/10/90	EP
GB 2 239 243 A	6/26/91	GB

Other Publications

Qui, et al., "Membrane Properties of Antiviral Phospholipids Containing Heteroatoms in the Acyl Chains," *Biochemistry* 1994, 33(4), 960-72.

Hostetler, et al., "Synthesis and Antiretroviral Activity of Phospholipid Analogs of Azidothymidine and Other Antiviral Nucleosides," *Journal of Biological Chemistry*, Vol. 265, No. 11, 15 April 1990, 6112-6117.

Jia, et al., "Diamide Analogs of Phosphatidylcholine as Potential Anti-AIDS Agents," *J. Chem. Soc. Perkin Trans. 1* (1993), 2521-23.

Hostetler, et al., "Phosphatidylazidothymidine, Mechanism of Antiretroviral Action in CEM Cells," *Journal of Biological Chemistry*, Vol. 266, No. 18, 25 June 1991, 11714-11717.

Hostetler, et al., "Phosphatidylazidothymidine and Phosphatidyl-ddC: Assessment of Uptake in Mouse Lymphoid Tissues and Antiviral Activities in Human

Immunodeficiency Virus-Infected Cells and in Rauscher Leukemia Virus-Infected Mice," *Antimicrobial Agents and Chemotherapy*, Dec. 1994, 2792-2797.

Amari, et al., "Isolation of Experimental Anti-AIDS Glycerophospholipids by Micro-Preparative Reversed-Phase High-Performance Liquid Chromatography," *Journal of Chromatography*, 590 (1992), 153-161.

Steim, et al., "Lipid Conjugates of Antiretroviral Agents. I. Azidothymidine-Monophosphate-Diglyceride: Anti-HIV Activity, Physical Properties, and Interaction with Plasma Proteins," *Biochemical and Biophysical Research Communications*, Vol. 171, No. 1, 1990, 451-457.

Painuly, et al., "Preparative HPLC of an Experimental Anti-HIV Analogue of AZT: Azidothymidine Monophosphate Diglyceride (AZT-MP-DG)," *Journal of Liquid Chromatography*, 16(11), 2237-2248 (1993).

Van Wijk, et al., "Synthesis and Antiviral Activity of 3'-azido-3'-deoxythymidine Triphosphate Distearoylglycerol: A Novel Phospholipid Conjugate of the Anti-HIV Agent AZT," *Chemistry and Physics of Lipids*, 70 (1994) 213-222.

Tarnowski, et al., "Effect of Lyso Lecithin and Analogs on Mouse Ascites," *Cancer Research*, Vol. 38 (1978), 339-344.

Berdel, et al., "Cyto Toxicity of Thio Ether Lyso Phospho Lipids in Leukemias and Tumors of Human Origin," *Cancer Research*, Vol. 43 (1983), 5538-5543.

Runge, et al., "Destruction of Human solid Tumors by Alkyl Lyso Phospho Lipids," *Journal of the National Cancer Institute*, Vol. 64 (1980), 1301-1306.

Hayashi, et al., "Antitumor Activity of a Novel Nucleotide Derivative, 5'-(1,2 Dipalmitoyl-*sn*-glycero-3-phospho)-5-fluorouridine (TJ14026) on Murine Tumors," *Biol. Pharm. Bull.*, 16(8), 778-81 (1993).

Sidoti, et al., "Cytostatic Activity of New Synthetic Anti-Tumor AZA-Alkyllysophospholipids," Int. J. Cancer 51, 712-717 (1992).

Jahne, et al., "Preparation of Carbocyclic Phosphonate Nucleosides," Tetrahedron Letters, Vol. 33, No. 37, 5335-5338 (1992).

Coe, et al., "Preparation of Nucleotide Mimics with Potent Inhibitory Activity Against HIV Reverse Transcriptase," J. Chem. Soc. Perkin Trans 1 (1991), 3378-3379.

Pajouhesh, et al., "Synthesis of Polar Head Group Homologs of All-*trans*-cyclopentano-phosphatidylcholine, Phosphatidyl-N, N-Dimethylethanolamine, and Phosphatidylethanolamine," Journal of Lipid Research, Vol. 25 (1984), 294-303.

Lister, et al., "Cyclopentanoid Analogs of Phosphatidylcholine: Susceptibility to Phospholipase A<sub>2</sub>," Journal of Lipid Research, Vol. 29 (1988), 1297-1308.

Hancock, et al., "Analogues of Natural Lipids. VII. Synthesis of Cyclopentanoid Analogs of Phosphatidylcholine," Journal of Lipid Research, Vol. 23 (1982), 183-189.

Mertes, et al., "Charge-Spatial Models. *cis*- and *trans*-3- and -4- Substituted Cyclohexyl Phosphates as Analogs of 2'-Deoxyuridine 5'-Phosphate," J. Med. Chem (1968), Vol. 12(5), 828-832.

Jayasuriya, et al., "Design, Synthesis, and Activity of Membrane-Disrupting Bolaphiles," J. Am. Chem. Soc. 1990, 112, 5844-5850.

Applicant respectfully requests that these items be considered by the Examiner, and that the Examiner acknowledge consideration of these references by initialing and returning copies of the enclosed Form PTO-1449 (3 sheets) with the next official action.

While this Information Disclosure Statement may be "material" pursuant to 37 C.F.R. §1.56, it is not intended to constitute an admission that any patent, publication or

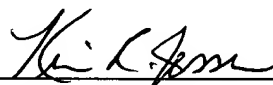
other information referred to herein is "prior art" for this invention or otherwise material to the patentability of this invention as defined in 37 C.F.R. § 1.56.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56(b) exists.

**EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

May 1, 2003  
Date

By:   
Kim R. Jessum  
Reg. No. 43,694  
Customer No. 028977  
MORGAN, LEWIS & BOCKIUS, LLP  
1701 Market Street  
Philadelphia, PA 19103-2921  
Telephone: (215) 963-4753  
Facsimile: (215) 963-5299